**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| UNITED STATES OF AMERICA, *ex rel.* SARAH BEHNKE,<br><br>Plaintiffs,<br><br>v.<br><br>CVS CAREMARK CORP. (n/k/a CVS HEALTH CORP.); CAREMARKPCS HEALTH LLC; CVS CAREMARK PART D SERVICES, LLC; and CAREMARK RX, LLC (f/k/a CAREMARK RX, INC.),<br><br>Defendants. | Civil Action No. 14-cv-824 (MSG) |

**DEFENDANTS' PROPOSED CONCLUSIONS OF LAW**

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## I. Introduction

Through eight days of evidence and 19 witnesses, Relator did not meet her burden of proof on any element in dispute. Not only did Relator offer no "smoking gun." ECF 339 ("SJ") at 88. The evidence showed no scienter, because no Caremark employee knowingly submitted false claims; and no materiality, because the government knew the relevant facts and did not disagree with Caremark's price reporting. The evidence as to either scienter or materiality is sufficient to resolve this case in Defendants' favor. Further, trial revealed Relator cannot meet her burden to show causation as to Aetna, falsity as to CVS Pharmacy, the involvement of CVS Health Corporation, or quantifying damages.

## II. Relator Has Not Proved Falsity as to CVS Pharmacy

At summary judgment, the Court reasoned that contractual GER guarantees to Walgreens and Rite Aid were the prices Caremark "actually paid" because "Caremark's overall indebtedness to th[ose] pharmac[ies] would increase by the negotiated average price for each purchase, regardless of what price Caremark put down at the time of sale." *Id.* at 69. As to CVS Pharmacy, the Court identified three unresolved issues: (1) whether Caremark was "obligated" to meet the budgeted GER, (2) whether Caremark and CVS Pharmacy "negotiated" a budgeted GER, and (3) what the budgeted GERs for 2013-2016 were. *Id.* at 70-71.

Relator did not establish any of these points at trial. The evidence is clear that the non-contractual budgeted GERs were neither "obligatory" nor the product of arm's length negotiations. The record does not even show what the budgeted amounts actually were.

***The budgeted GERs were not obligatory***. ***First***, unlike contractual guarantees, there were no financial consequences if Caremark missed budgeted GERs. Defs.' Falsity Fact 6. Caremark *did* miss the budgeted GER and *did not* owe money to CVS Pharmacy. 3/14/25 Tr. 73:4-75:2. The only payment Relator points to is Caremark's transfer of $13 million to CVS

Pharmacy in 2016. Defs.' Resp. to Rel.'s Falsity Fact 7. That payment was a result of Caremark's increased MAC pricing for "spread" commercial clients, not Medicare Part D clients. *Id*.; 3/17/25 Tr. 32:21-33:9. There is no evidence of payments in any other year. Thus, budgeted GERs were merely targets with no consequences if not met. Defs.' Falsity Facts 6-8.

***Second***, the budgeted GERs were flexible and changed throughout the year. *Id*. at Fact 7. Caremark and CVS Pharmacy had no static annual GER commitment, or even a static target—more proof the budgeted GER did not bind Caremark or CVS Pharmacy. *Id*. The Court's falsity reasoning—that higher Part D payments "reduce[] the reconciliation payment that Caremark would otherwise have to make" to pharmacies, SJ 61—simply does not apply to CVS Pharmacy.

***The budgeted GERs were not negotiated***. Unlike Walgreens' and Rite Aid's GER guarantees, which were contractual and guaranteed an aggregate floor for reimbursement, the purpose of CVS Pharmacy's budgeted GER was to align the budget assumptions of Caremark and CVS Pharmacy, which rolled up into CVS Health's consolidated financial reporting. Defs.' Falsity Facts 1-5; 3/14/25 Tr. 135:7-13, 148:5-12. Accordingly, there was no true negotiation between Caremark and CVS Pharmacy. Instead, Eva Boratto conveyed their strategic goals and expected business mix to CVS Health CFO, David Denton; senior executives, including Denton, then set budget assumptions based on the overall benefit to the entire CVS Health corporate family. 3/14/25 Tr. 136:20-137:6, 148:13-149:21; Defs.' Falsity Fact 5. The budgeted GER process does not resemble the arm's length negotiations that produced the Walgreens and Rite Aid GER guarantees. *See* Defs' Falsity Fact 5; Defs' Scienter Fact 5.

***Relator lacks competent evidence of the budgeted GER***. Without clearly identifying what the budgeted GERs were, Relator cannot prove Caremark overcharged CMS by exceeding them. *Id.* at Fact 11. ***First***, as Eva Boratto, Domenico Gugliuzza, and John Lavin testified, the

budgeted GER could and did change throughout the year. *Id.* at Fact 7 (collecting testimony); *see also id.* at Fact 10. Relator's expert, Loren Smith, did not account for that at all. ***Second***, Smith did not rely on a consistent set of documents to identify the purported budgeted GER for each year, and his rationales for picking documents were arbitrary. *Id.* at Facts 12-14; Defs.' Damages Facts 13-17; *see also infra* Section VI.C (discussing Smith's 2013-14 methodology).

## III. Relator Has Not Proved Materiality

The materiality standard is "rigorous" and "demanding," requiring "strict enforcement." *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 192, 194 (2016). Relator must prove that Caremark "knowingly violated a requirement that [Caremark] kn[ew] is material to the Government's payment decision." *Id.* at 181. Relator's burden is discussed in detail in Defendants' Bench Memorandum on this subject. *See* ECF 455-1 (discussing burden, relevant actor, time period, and significance of government inaction and non-intervention). Critically, Relator must prove materiality for the misrepresentation—not just the claim. SJ 77. Thus, a misrepresentation is not "automatically material" merely because it "cause[d] the Government to overpay." *Id.* As this Court expressly held, Relator "must establish" something more specific: "that had CMS known of Caremark's guaranteed average pricing terms and the corresponding mismatch with reported prices, such knowledge would have had a 'likely' 'effect' on CMS's payment decisions." *Id.* at 78 (citation omitted).

### A. The Government Has Signaled No Change in Position

If the government "signal[s] no change in position," and "regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, . . . that is strong evidence that the requirements are not material." *Escobar*, 579 U.S. at 195. And "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is *very strong evidence* that those requirements are not material." *Id.*

(emphasis added). Even when the government "may not have independently verified [the defendant's] noncompliance—and thus may not have obtained 'actual knowledge' of the alleged infractions—its inaction in the face of detailed allegations" still signals "immateriality." *U.S. ex rel. Janssen v. Lawrence Mem'l Hosp.*, 949 F.3d 533, 542 (10th Cir. 2020); *U.S. ex rel. Stebbins v. Jefferson Cardiology Ass'n*, 2024 WL 3982318, at *5 (W.D. Pa. Aug. 29, 2024) (same). While government inaction is not always dispositive as a matter of law, *see U.S. v. Care Alternatives*, 81 F.4th 361, 375 (3d Cir. 2023), "continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality," *U.S. ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 663 (5th Cir. 2017) (collecting cases); *see U.S. ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017).

Time and again, the Centers for Medicare & Medicaid Services ("CMS"), the "paying agency . . . with oversight and enforcement authority," *U.S. ex rel. Krahling v. Merck & Co.*, 2024 WL 3664648, at *7 (3d Cir. Aug. 6, 2024), was told the facts the Court later found made the price-reporting false. And time and again, CMS declined to take action in response.

***CMS did not change its payment decisions after Caremark disclosed its one-way guarantees.*** In early 2016, CMS officials questioned PBMs about pharmacy GER guarantees. Defs.' Mat. Fact 3. On a March 8, 2016 call with Caremark, CMS officials explained their concern: whether PBMs were "clawing back" money from pharmacies. *Id.* at Fact 4. Caremark's David Azzolina told CMS that Caremark's guarantees did *not* allow clawbacks since Caremark did not receive payments from pharmacies. *Id.* at Fact 5; 3/17/25 Tr. 114:3-115:4. CMS appeared satisfied. Defs.' Mat. Fact 5.

A few months later, on May 26, 2016, the same pattern played out via email. DX001.0001. ***First***, Azzolina reiterated to CMS that the guarantees were one-way: Caremark

could make a year-end reconciliation payment to a pharmacy, but not the other way around. Defs.' Mat. Fact 6. ***Second***, he explained that the guarantees applied "across the pharmacy book of business with the PBM." *Id.* at Fact 7. Fact and expert witnesses explained that the industry term "book of business" includes both commercial and Part D, and Relator has offered no evidence of a different interpretation. *Id.* (collecting testimony). ***Third***, Azzolina explained (i) "[t]he amount that Part D plans pay to CVS Caremark is based on the contractual agreement between the plan and [Caremark] and is not altered by the guarantee to the pharmacy," (ii) Part D plans paid Caremark the same price Caremark "paid to the pharmacy at point of sale," and (iii) point-of-sale prices were "recorded on the PDE." DX001.0001; *see* Defs.' Mat. Fact 8.

Again, CMS appeared satisfied. 3/17/25 Tr. 84:23-24; Defs.' Mat. Fact 9. Several times in the ensuing months, CMS and Caremark discussed price reporting. Defs.' Mat. Fact 9; DX002.0001. CMS never asked follow-up questions about pharmacy guarantees, never asked to see Caremark's pharmacy contracts, and never indicated it had any other concerns. *See* Defs.' Mat. Fact 9. CMS's response is particularly probative because Azzolina's lead contact was Cheri Rice, the top CMS career official over Part D plans, who oversaw the agency's guidance on reporting direct and indirect remuneration. *Id*. at Fact 4; 3/18/25 Tr. 185:10-13; DX219.0001.

***CMS did not change its payment decisions after auditing Aetna.*** In February 2015, CMS auditors learned about Aetna's investigation. Defs.' Mat. Fact 12. CMS auditors can investigate a plan's PBM and review the PBM's pharmacy contracts. *Id*. at Fact 11. There is no evidence they sought to do so here. Nor did their final report note any issue concerning Caremark's pharmacy GER guarantees. *Id*. at Fact 14. Instead, the CMS auditors concluded, with one irrelevant exception unrelated to pharmacy GER guarantees, that Aetna's PDE and DIR reports were "fairly stated, in all material respects." *Id.*; DX210.0003.

Relator implausibly claims the auditors did not receive a "complete or fulsome explanation." Rel.'s Resp. to Defs.' Mat. Fact 12. Relator herself attested, in language she proposed: "[W]e have identified to the CMS auditors . . . that we are reviewing with CVS/Health the specifics of their global pharmacy arrangements and the potential impact on PDEs and/or DIR." Defs.' Mat. Fact 13; 3/12/25 Tr. 100:6-102:8. Relator testified: "I mentioned that there was an ongoing investigation, but that the auditors said, oh, we're aware. John Wells described this to us." 3/13/25 Tr. 61:1-3; *see also* DX207.0001 (talking points for Wells' meeting). Wells was not "some midlevel compliance guy[]" as Relator claimed. 3/13/25 Tr. 61:10-62:4. He was Aetna's Chief Medicare Compliance Officer. Defs.' Mat. Fact 12.

Regardless, the auditors did not just meet with Wells, they also met with Relator. And here, Relator's story has shifted. At her deposition, she claimed not to remember the conversation. 3/12/25 Tr. 168:22-169:3. At trial, Relator claimed "a typo" in an exhibit had thrown her off, and now alleges that Aetna's deputy general counsel, Charlie Klippel, "coached" her. 3/13/25 Tr. 57:14-21; 3/12/25 Tr. 167:23-168:1. Relator's revisionism is not credible, especially since she met with the auditors *one year after she filed this lawsuit*. 3/13/25 Tr. 57:22-58:5. Relator had every opportunity and incentive to explain her concerns to the auditors.

***CMS did not change its payment decisions following Relator's lawsuit.*** After Relator filed her sealed complaint in 2014, two government agencies investigated. Defs.' Mat. Fact 15. Relator did not withhold any information. *Id.* The government declined to intervene. ECF 24. The government filed a statement of interest at summary judgment, which expressly declined to "express a view" on Relator's interpretation of the regulations. ECF 312 at 4. Nor did the government take a position on materiality—despite taking positions on other issues. SJ 79 n.34.

"[T]he government's decision not to intervene, coupled with additional relevant

government action or inaction, is strong evidence in favor of finding that the materiality element has not been met." *U.S. ex rel. Stebbins v. Vascular Access Centers, LLC*, 2024 WL 3069902, at *9 (W.D. Pa. June 20, 2024) (collecting cases). This applies with particular force here, since the government conducted a four-year investigation. *Id.*; *compare* ECF 1, *with* ECF 24.

Despite its clear knowledge of the relevant facts from multiple sources and at multiple times, CMS did not commence any enforcement action, seek to recover any subsidies, or initiate any audits based on Caremark's pharmacy GER guarantees. Defs.' Mat. Facts 17-18. Nor did CMS publish any new regulations, guidance, or other statements to address one-way pharmacy GER guarantees, or even ask more questions of Caremark. *Id*. at Facts 18-19. The evidence, then, shows more than "inaction," *Stebbins*, 2024 WL 3069902 at *9; it shows repeated, affirmative decisions *not* to act, *see Janssen*, 949 F.3d at 538, 542 (no materiality where the relator "called a CMS hotline," "a third-party investigative service for CMS, subsequently began investigating the allegations," but "[t]o this day, CMS has done nothing in response").

As Relator admits, CMS is a sophisticated agency that frequently interacts with the industry. Defs.' Mat. Facts 1-2. CMS does not hesitate to express questions and concerns about price-reporting issues. *Id.* at Fact 10. CMS also has an arsenal of tools at its disposal to ensure compliance with its regulations. *Id*. at Fact 17. The "decision not to employ these tools in the wake of Relator['s] allegations . . . renders a claim of materiality implausible." *U.S. ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 34 (1st Cir. 2017) (citation omitted).

**B. Relator's Evidence Is Unavailing**

Although materiality turns on CMS's decisions, Relator often omits CMS from her proposed materiality facts. Relator focuses on what Aetna supposedly understood, what Caremark supposedly did not provide to Aetna, or what may be "material and important" as a general matter. Rel.'s Mat. Facts 6-8. But none of these facts addresses the key issue: whether

the misrepresentation had a likely effect on CMS's payment decisions. SJ 78.

On *that* issue, Relator makes only two arguments, and neither is persuasive. ***First***, Relator notes accurate price reporting "was an express condition of payment." Rel.'s Mat. Fact 4. But "[a] misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment." *Escobar*, 579 U.S. at 194. And the condition Relator cites is as general as they come; it required data to be "accurate, complete, and truthful." 42 C.F.R. § 423.505(k)(3); *see* 42 C.F.R. § 423.322(a) (cited at Rel.'s Mat. Fact 4).

***Second***, Relator claims Caremark "caused the government to overpay Medicare Part D subsidies by between $242 million and $338 million." Rel.'s Mat. Fact 14. "[C]aus[ing] the Government to overpay" does not make a misrepresentation "automatically material." SJ 77. To argue otherwise "conflates materiality with causation," and confuses materiality of the *claim amount* with materiality of the *misrepresentation*. *See Petratos*, 855 F.3d at 491; *see also* SJ 77.

When assessing materiality, "we have the benefit of hindsight and should not ignore what actually occurred." *U.S. ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1034 (D.C. Cir. 2017). If CMS *really* considered the misrepresentation material—and thought a failure to report prices according to pharmacy GER guarantees had cost it hundreds of millions of dollars—why did CMS not do *anything* about it? In multiple years, from multiple sources, and over a decade, the government repeatedly heard all of the facts and refused to enforce Relator's reading of its regulations. *Supra* pp. 3-7; *see U.S. ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 764 (3d Cir. 2017) (no materiality where "CMS was well aware" of the facts but "took no action").

## IV. Relator Has Not Proved Causation as to Aetna

"[T]he causation element cannot be met merely by showing 'but for' causation." *Petratos*, 855 F.3d at 491. Relator must establish proximate causation, which requires proof that

Caremark "was a 'substantial factor' in causing the submission of a false claim." SJ 81 (quoting *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3d Cir. 2004)). Caremark was not a substantial factor for two reasons.

***First***, under Medicare regulations, a "Part D sponsor" like Aetna "maintains ultimate responsibility" for compliance, "[n]otwithstanding any relationship(s) that [it] may have" with a PBM like Caremark. 42 C.F.R. § 423.505(i)(1). Or, as Relator put it, "it is our [Aetna's] job to police the PBM." PTX-299 at 2; *see also* Defs.' Caus. Facts 1-2. Relevant to PDEs, Aetna operated its own in-house "claims adjudication system." Defs.' Caus. Fact 5. That system calculated the amounts Aetna would report to CMS on the PDEs. *Id*. at Facts 5-6. As for DIR, Aetna filled out its own reports, and supplied much of its own data. *Id*. at Fact 7. Although Caremark provided some data to Aetna in DIR templates, Caremark did not "provide[] price reports to Aetna with the intention that they be forwarded to CMS unmodified." SJ 83; *see* Defs.' Caus. Fact 8. Caremark expected that Aetna, as the Part D Sponsor, would review, adjust, and submit those DIR reports itself. Defs.' Caus. Fact 8. In this respect, Relator has not advanced her case from summary judgment. Using the exact same evidence as at that stage, she has not shown that Aetna somehow "'implement[ed]' Caremark's 'instructions' on its 'system,'" such that she could prove proximate causation. SJ 83.

***Second***, Aetna made an independent judgment not to revise reporting to reflect Caremark's pharmacy GER guarantees. Consistent with its strong compliance culture and its business and regulatory incentives, Aetna conducted a thorough investigation. Defs.' Caus. Facts 3-4, 9. Aetna asked questions of Caremark, hired a respected and plan-friendly auditing firm (Burchfield), and engaged a preeminent, now-deceased healthcare-law expert (Art Lerner of Crowell & Moring). *See id.* at Facts 9-13. Through that years-long investigation, Aetna learned

all the facts the Court later found made the price-reporting false. *See id*. at Facts 11-12. In 2015, Aetna made an independent decision to continue to (1) report point-of-sale prices on PDEs and (2) not report any amounts on DIR reports related to Caremark's pharmacy GER guarantees. *See id*. at Fact 14. Because of that independent judgment, Caremark was not a substantial factor.

Alternatively, the Court should find that a superseding cause broke the chain of causation. *See* SJ 82; *Johnson v. City of Philadelphia*, 837 F.3d 343, 351-52 (3d Cir. 2016). Given Aetna's control over its PDE and DIR reporting, its preparation of DIR reports, its independent judgment to continue reporting in the same way following a years-long investigation, and Caremark's expectation that Aetna would review, adjust, and submit claims itself, the submission of false claims was not the "normal consequence" of Caremark's conduct. SJ 83. Additionally, the extensive government inaction "leaves Relator[] with a break in the causal chain." *Nargol*, 865 F.3d at 34; *see supra* pp. 4, 7.

## V. Relator Has Not Proved Scienter

### A. Requirements to Establish Scienter

Relator has the burden to prove that Caremark "knowingly" caused the submission of a false claim. 31 U.S.C. § 3729(b)(1)(A). The scienter requirement is "rigorous," *Escobar*, 579 U.S. at 192, and focuses on the defendant's "knowledge and subjective beliefs," *U.S. ex rel. Schutte v. SuperValu, Inc.*, 598 U.S. 739, 749 (2023). There are three potential paths to prove a defendant's subjective knowledge: **Actual knowledge** means the defendant was "aware" the claim was false. *Id.* at 751 (citation omitted). **Deliberate ignorance** "encompasses defendants who are aware of a substantial risk that their statements are false, but intentionally avoid taking steps to confirm the statement's truth or falsity." *Id.* **Reckless disregard** "captures defendants who are conscious of a substantial and unjustifiable risk that their claims are false." *Id.*

To establish corporate scienter, Relator must prove at least one "agent of the corporation

committed a culpable act with the requisite scienter," and show "that the act (and accompanying mental state) are attributable to the corporation." *Teamsters Loc. 445 Freight Div. Pension Fund v. Dynex Cap. Inc.*, 531 F.3d 190, 195 (2d Cir. 2008). Relator may not combine different employees' acts and knowledge and thus "attribute to a corporation a state of mind that none of its employees had." *Makor Issues & Rights, Ltd. v. Tellabs Inc.*, 513 F.3d 702, 707-08 (7th Cir. 2008); *see also U.S. v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1275 (D.C. Cir. 2010).

**B. Relator's Evidence Did Not Prove Any of the Paths to Scienter**

The evidence at trial cannot support a finding of actual knowledge, deliberate ignorance, or reckless disregard. As the Court held at summary judgment, it was not enough for Relator to prove Caremark employees knew the facts that Relator now claims amounted to unlawful conduct. SJ 85. Instead, Relator needed to identify a particular Caremark employee who (a) was aware of the pricing information Caremark relayed; *and* (b) was aware—or at least was conscious of a substantial and unjustifiable risk—that, as a matter of law, claims submitted based on that information would be false. *Id.*; *see supra* 10-11 (collecting cases).

Relator did not identify a Caremark employee with scienter. To the contrary, each Caremark witness at trial testified, credibly, that he or she had no culpable mental state, and the documentary and industry evidence fully supported that testimony.

**1. There is no evidence anyone at Caremark had actual knowledge**

Relator presented no evidence that any person at Caremark actually believed the reporting was false. Every Caremark employee was unanimous in this regard. Defs.' Scienter Facts 1-3, 7, 10-11, 14-16. To find scienter, the Court would effectively have to conclude that these Caremark witnesses—Azzolina, Brown, Gugliuzza, Justice, Kinney, Lavin, and Margiotta—were lying. But the testimony of Caremark witnesses was consistent with documents from the 2010-2016 time period. Defs.' Scienter Facts 1, 7, 10-11, 14, 16; DX006;

DX008.0001; DX127.0002; DX212. Then and now, Caremark employees honestly believed that they acted properly. The Court at summary judgment opined Relator had no "'smoking gun' document from Caremark admitting to (or even acknowledging the possibility of) an interpretation of CMS's regulations at variance with Caremark's own." SJ 88. The same is true of the testimony and documents Relator elicited at trial.

**2. There is no evidence anyone at Caremark was deliberately ignorant**

There is similarly no evidence that any Caremark employee was "aware of a substantial risk that their statements [were] false, but intentionally avoid[ed] taking steps to confirm the statement's truth or falsity." *Schutte*, 598 U.S. at 751. Knowledge that an opposing viewpoint exists is not enough. "The defendant must subjectively believe that there is a high probability" that it is relaying a falsehood, such that the defendant "can almost be said to have actually known the critical facts." *Glob.-Tech Appliances, Inc. v. SEB S.A.,* 563 U.S. 754, 769-70 (2011).

Nothing suggests any Caremark employee acted with this state of mind. Evidence demonstrated Caremark employees believed the company's approach to MAC pricing, plan GER guarantees, and pharmacy guarantees was proper. Defs.' Scienter Facts 1-4, 7-12, 17-18, 21. Indeed, Relator *admits* that Caremark witnesses "did not believe prices to the Medicare Part D plan (i.e., Aetna) had to be set . . . based on the pharmacy GER guarantee percentage." Rel.'s Resp. to Defs.' Scienter Fact 10 (emphasis omitted).

**3. There is no evidence anyone at Caremark was conscious of a substantial and unjustifiable risk**

Relator also adduced no evidence that any Caremark employee was "conscious of a substantial and unjustifiable risk" of falsity. *Schutte*, 598 U.S. at 751. This state of mind requires more than a difference of opinion or "a bad mistake." *Counterman v. Colorado*, 600 U.S. 66, 80 (2023). If a company takes a good-faith position that turns out to be wrong, it does

not behave recklessly, even if the position was favorable to the company. *See U.S. ex. rel. Marshall v. Woodward, Inc.*, 812 F.3d 556, 561-62 (7th Cir. 2015).

As at summary judgment, there is no evidence that anyone at Caremark even "acknowledge[ed] the possibility" that Caremark's reporting might be false. SJ 88. Instead, the trial record confirms Caremark employees—like other sophisticated industry participants—did not think they needed to set each plan's MAC prices to meet pharmacy GER guarantees, did not think they were earning spread on Part D drugs, and did not otherwise think that their actions were improper. Defs.' Scienter Facts 1-2, 7, 10, 16.

***Caremark employees believed they were correct and had no reason to conclude otherwise.*** No Caremark employee perceived any substantial risk that Caremark's price reporting might be inaccurate, *supra* at 11-12, and their belief was entirely reasonable and therefore credible. Caremark tracked CMS guidance on price reporting. 3/13/25 Tr. 183:6-185:8; 187:9-18. Prior to this Court's decision, neither CMS nor any other authority ever took the position that Caremark needed to report "average aggregate prices" rather than individual sale prices for Part D claims. Defs.' Scienter Fact 3; *accord* Rel.'s Resp. to Defs.' Scienter Fact 3. Relator has not shown that industry participants perceived CMS regulations differently, or that Caremark interpreted regulations in bad faith. *Supra* at 11-12; *see Hagood v. Sonoma Cnty. Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1996). At most, Caremark learned that an Aetna employee expressed concerns, that Aetna thoroughly investigated those concerns, and that Aetna concluded its price-reporting was appropriate. Defs.' Scienter Facts 4, 20-25; DX005.004. It was not "unjustifiable" for Caremark's employees to credit their own conclusion, the lack of contrary guidance, and Aetna's reasoned conclusion over Relator's accusation.

***Caremark employees did not see industry-standard price-setting as a wrongful***

***"scheme."*** Putting aside the regulatory interpretation, there is no evidence anyone at Caremark believed they were setting Medicare Part D prices higher to "offset" lower commercial prices or to earn improper "spread." Defs.' Scienter Facts 14-16. Caremark set guarantees for each plan and each pharmacy based on the market, *id*. at Facts 7, 9, 14, and saw the plan and pharmacy guarantees as a downside for Caremark rather than as a profit opportunity, *id*. at Facts 12-13. No one thought prices needed to be set based on a pharmacy GER guarantee. *Id*. at Fact 10. Witnesses further explained that if Caremark had *tried* to increase Part D prices as Relator claims, Caremark would have lost Part D clients during the competitive bidding process. *Id*. at Fact 9. And when asked by CMS, Azzolina readily (and repeatedly) told the regulator about Caremark's pharmacy GER guarantees—further proof that no one at Caremark was conscious of a substantial and unjustifiable risk of falsity. *Supra* at 4-5.

Relator's counsel promised Rite Aid—a counterparty pharmacy—"understood this offsetting perfectly and will testify to it." 3/10/25 Tr. 14:5-7 (opening statement). Yet on the stand, Rite Aid's representative testified it did *not* believe there was any "scheme" by Caremark, and it did not see significant differences between Caremark's Part D prices versus commercial prices, or between Caremark's and other payors' Part D prices. Defs.' Scienter Fact 19.

Relator identified no industry participant (other than herself) who ultimately disagreed with Caremark's understanding of CMS requirements. Instead, industry-practice evidence at trial corroborated Caremark employees' sincere belief that they were doing nothing wrong. *See U.S. ex rel. Patzer v. Sikorsky Aircraft Corp.*, 722 F. Supp. 3d 839, 854 (E.D. Wisc. 2024); *see also* ECF 412 at 11. Leslie Norwalk, the former Acting Administrator of CMS, testified she would not have expected industry participants to think one-way pharmacy GER guarantees triggered PDE or DIR reporting obligations. 3/18/25 Tr. 156:7-158:17; *id.* at 141:3-142:14. And

CMS took no action against Caremark after being told by both Caremark and Aetna about the price-reporting. Defs.' Scienter Fact 21; Defs.' Mat. Facts 3-16, 18.

Aetna, a Part D sponsor with its own business and regulatory incentives to correctly report prices, thoroughly investigated Caremark's conduct. Defs.' Scienter Facts 4, 20-25; Defs' Causation Fact 4. After that investigation, Aetna decided to continue price-reporting in the same way. Defs.' Scienter Facts 4, 20-25; Defs' Causation Fact 4; DX008. Aetna made this judgment with the knowledge that (i) Caremark's pharmacy GER guarantees covered Part D and commercial claims and (ii) Caremark's pharmacy GER guarantees would sometimes reflect a deeper aggregate discount off AWP than Aetna's Part D plans. Defs.' Scienter Facts 22, 25. And when Aetna took pharmacy contracting in-house, it continued to report point-of-sale prices on PDEs, and its DIR reporting was based on Aetna's new *two-way* pharmacy guarantees (where pharmacies would have to pay Aetna). Defs.' Scienter Fact 25.

***The actual pricing and contracting is utterly inconsistent with the alleged scheme.*** If Caremark had viewed overall pharmacy GER guarantees as a way to profit from Part D pricing, it would have tried to make similar agreements with all pharmacies, every year. Caremark did not do so, underscoring its innocent state of mind. And the actual pricing patterns for Part D and commercial claims—both in year-pharmacy combinations when Caremark had overall GER guarantees and when it did not—are directly inconsistent with any scheme.

***First***, Relator's claims implicate reporting as to only a few pharmacy chains for only a few years (years that differ for each pharmacy). Defs.' Scienter Facts 6; Stips. 114, 115, 116, 120, 121. Caremark agreed to pharmacy GER guarantees with Walgreens and Rite Aid because those pharmacies demanded them, Defs.' Scienter Fact 5, and Caremark employees did not view pharmacy GER guarantees as a profit opportunity, *id*. at Fact 12.

***Second***, even within that limited set of pharmacies and years, Defs.' Scienter Fact 6; ECF 463-1 at DD11.4 and DD11.5, there are some years for which Relator seeks no damages because the plan *paid less for Part D drugs* than the overall discount rate in the pharmacy GER guarantee. Defs.' Damages Fact 19; ECF 463-1 at DD11.4 ("No Pricing Discrepancy"). Additionally, Caremark often paid more for Medicare Part D drugs than for commercial drugs *even when Caremark did not have an overall pharmacy GER guarantee*. Defs.' Scienter Facts 17-18; Rel.'s Resp. to Defs.' Scienter Fact 18. These undeniable facts show the variance between Part D and commercial rates was driven by market factors, not a scheme.

***Third***, Caremark's price-reporting remained consistent. There is no evidence that Caremark altered its price reporting from client-to-client or from plan-to-plan, regardless of whether it had an overall GER guarantee. All of this shows no one at Caremark was aware of a substantial and unjustifiable risk that CMS regulations required different price reporting.

## VI. Relator Has Not Proved Damages

Relator's failures of proof preclude damages for all pharmacies and all years.

### A. Relator Has Not Proved Damages Based on "False" PDEs

***Relator has not proved PDEs were false claims.*** The False Claims Act requires "evidence of the actual submission of a false claim," *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 98 (3d Cir. 2018), which was false "when it was originally submitted," *U.S. ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 439 (3d Cir. 2004). ***First***, PDEs reflected point-of-sale prices and were accurate. PDEs are tied to individual transactions, and therefore must reflect the price paid to the pharmacy and passed through to Aetna and SilverScript at the point of sale. Defs.' Damages Fact 2; Defs.' Mat. Fact 8; 3/13/25 Tr. 216:25-217:4, 3/14/25 Tr. 55:2-6. It would have been inaccurate to report pharmacy GER guarantees in PDEs, because they do not reflect the point-of-sale price. Defs.' Damages Facts 1-4.

***Second***, as the Court determined, PDEs and DIRs must "*collectively* . . . reflect[] Caremark's guaranteed average prices." SJ 63 (emphasis added); *see* Defs.' Damages Fact 3. While PDEs are reported after every transaction, DIR reports are submitted at the end of the year. Defs.' Damages Facts 2, 8; 3/18/25 Tr. 138:6-140:21. There was no failure to report pharmacy GER guarantees unless and until the DIR reports did not reflect those guarantees. ***Third***, Relator has never identified any false PDE. Smith considered PDEs in the aggregate. Defs.' Damages Fact 7; Defs.' Resp. to Rel.'s Damages Fact 16. But an aggregate analysis does not prove the falsity of any individual PDE; in fact, many PDEs reported lower prices than the pharmacy GER guarantee. Defs.' Damages Fact 5. Because PDEs could not have reflected pharmacy GER guarantees, their submission did not *cause* any alleged overcharge (as the FCA requires). *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 183-84 (3d Cir. 2001).

***Relator has not proved PDE-based damages.*** Even if the PDEs were false, Relator did not prove PDE damages "with reasonable certainty." *U.S. v. Sci. Applications Int'l Corp.*, 958 F. Supp. 2d 53, 77-78 (D.D.C. 2013). "Calculations based on mere speculation . . . do not provide a basis for relief." *U.S. ex rel. Int'l Bhd. of Elec. Workers, Loc. Union No. 98 v. Farfield Co.*, 2019 WL 7844585, at *28 (E.D. Pa. Nov. 29, 2019).

***First***, Smith calculated PDE damages in the aggregate "by adjusting four fields on the year-end, aggregate summary reports." Defs.' Damages Fact 7. But the "phase" of coverage for a transaction impacts the subsidies CMS pays for a particular drug, Defs.' Damages Fact No. 6, and Smith did not account for the impact of changing the prices reported on each PDE, Defs.' Damages Fact 7.[1] ***Second***, one set of Smith's damages calculations uses the plan GER guarantee

[1] For similar reasons, Smith's PDE calculations overstate the number of false claims. *See* Defs.' Damages Fact 5. Defendants understand the number of claims is outside the scope of the Court's briefing order and will address the issue in any later briefing on penalties, if necessary.

as a stand-in for the prices actually paid by Aetna and SilverScript. That methodology is improper because the amount the plan sponsors actually paid is determinable. Defs.' Resp. to Rel.'s Damages Fact 11, 20 (collecting testimony).

**B. Relator Has Not Proved DIR-Based Damages**

Relator's DIR-based damages claim similarly lacks reasonable certainty. ***First***, one of the DIR-based calculations also relies on the plan GER guarantees (rather than amounts actually paid by plan sponsors) and is speculative. *Supra* at 17-18. ***Second***, Smith relies on aggregate calculations at the plan-sponsor level when plan sponsors actually report DIR separately for each Part D plan. Defs.' Damages Facts 8-11. By aggregating DIR reports, Smith effectively attributes false claims and inflated prices to every individual plan for each year, *id.*, but in reality, 23% of the plan-year combinations Smith considered offered *better* pricing than the applicable pharmacy GER guarantee. *Id.*; *see also* 3/20/25 Tr. 43:14-44:8.[2] By, in effect, assuming that each plan was false, Smith over-allocated the pricing discrepancy essential to his damages calculation. Had he calculated damages at the level of actual reporting, he would have allocated $45 million less in damages to 231 of 673 plan-year combinations. Defs.' Damages Fact 12; B. Barlag, 3/20/25 Written Direct Affidavit ¶ 65.

**C. Relator Has Not Proved Damages as to CVS Pharmacy**

Relator's analysis of CVS pharmacy claims fails for the additional reason that Smith could not reliably identify a yearly budgeted GER. *See* Defs.' Damages Facts 13-17. Instead, Smith selected the budgeted GER from a varied set of documents or parts of documents, or had to manufacture his own. Defs.' Damages Facts 13-16. For example, Smith (for 2013) relied on a document with two different GERs, and selected the one leading to higher damages, despite

[2] For similar reasons, Smith's DIR damages calculations overstate the number of false claims and are not a reliable basis for determining statutory penalties. *See* Defs.' Damages Fact 9.

contrary fact testimony at trial. Defs.' Damages Fact 14; PTX190 at 1-2; 3/14/25 Tr. 146:1-147:15. The same page from which Smith selected his preferred budgeted GER explained that the budgeted GER for the following year, 2014, would increase by 1% (*i.e.*, to 80.8%). PTX-190 at 2. Yet Smith did not use that rate for 2014, instead choosing to calculate a budgeted GER that resulted in greater damages. Defs.' Damages Facts 15, 17; 3/17/25 Tr. 200:16-19. More than 60% of Relator's alleged damages are attributable to CVS Pharmacy. Rel.'s Damages Fact 18.

## VII. Relator Has Not Proved CVS Health Corporation's Liability

In addition to the above, Relator's claims against CVS Health Corporation fail because it had no "direct involvement in causing the submission of false claims to the government." *U.S v. Exec. Health Res., Inc.*, 196 F. Supp. 3d 477, 513 (E.D. Pa. 2016).

CVS Health Corporation is the indirect parent of the other defendants, Stips. 1-4, and it is hornbook law that a parent is not liable for the acts of its subsidiaries, *United States v. Bestfoods*, 524 U.S. 51, 61 (1998). Relator conceded CVS Health Corporation was not a signatory to any of the contracts at issue. Rel.'s Resp. to Defs.' CVS Health Facts 1, 3, 5-7; *see* SJ at 19-20. There is no evidence CVS Health Corporation had (or exercised) relevant duties or responsibilities under those contracts, Defs.' CVS Health Facts 1, 3, 5-8, or that it made any of the challenged price reports to the government, SilverScript, or Aetna, *id*. at Facts 2, 4.

Relator says "CVS Health Corporation" submitted attestations, but the attestations were made by "the Medicare Part D Organization," which was "SilverScript Insurance Company." PTX-210, PTX-211, PTX-212, PTX-213. There is no evidence any of the signatories was an officer or employee of CVS Health, and the only one to testify—Todd Meek—confirmed he was a SilverScript officer and Caremark employee. 3/18/25 Tr. 27:24-28:13; *id.* at 24:13-15, 21-22.

Relator says Jon Roberts (who did not testify), Eva Boratto, David Azzolina, and Allison Brown were employed by or officers of CVS Health Corporation. But the record shows that

Roberts and Boratto held officer positions with both the parent corporation and its PBM subsidiaries. 3/17/25 Tr. 98:23-25; 3/10/25 Tr. 141:9-13; PTX 0319 at 29; PTX 0319 at 3; 3/14/25 Tr. 130:15-131:23, 132:10-13. And both Azzolina and Brown testified the work they performed was for Caremark. 3/19/25 Tr. 171:1-172:1, 186:4-16; 3/17/25 Tr. 62:11-14. When personnel hold positions at the parent and subsidiary, the presumption is that they act on behalf of the subsidiary. *Bestfoods*, 524 U.S. at 69-70 (1998); *Czarnecki v. Krause*, Inc., 2008 WL 4083173, at *5 (E.D. Pa. Aug. 28, 2008). Relator has failed to overcome that presumption.

## VIII. Relator Has Not Proved Any Theory Under 31 U.S.C. § 3729

Relator's "false statement" claim under § 3729(a)(1)(B) is completely duplicative of her "false claim" theory under § 3729(a)(1)(A), and thus fails for the same reasons. Relator's "reverse" FCA claim under § 3729(a)(1)(G) also fails because it is redundant of her other FCA claims. *See U.S. ex rel. Petratos v. Genentech, Inc.*, 141 F. Supp. 3d 311, 322 (D.N.J. 2015) (redundant reverse FCA claims are impermissible), *aff'd*, 855 F.3d 481 (3d Cir. 2017). After the Court dismissed Relator's reverse FCA theory for this reason, ECF 78 at 20-21, Relator's amended complaint merely recast her claims as a potential obligation to refund money to the government, ECF 114 ¶¶ 149, 188-89. Relator's pretrial memorandum confirmed that Relator has no distinct "reverse" FCA claim. ECF 408 n.3.

## IX. Relator Has Not Met Her Burden of Proof

As amended, the False Claims Act allows "the United States" to prove its case "by a preponderance of the evidence." 31 U.S.C. § 3731(d). Under that standard, Relator has not met the burden for each of the elements discussed above. But Relator's burden is actually higher: In a non-intervened case, the pre-amendment, *clear-and-convincing evidence* standard should apply, given the Act's plain text and punitive nature. *See* J. T. Boese, *Civil False Claims & Qui Tam Actions* § 5.08 (5th Ed. 2024) (endorsing this approach).

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Respectfully submitted,

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